Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/518,914	**Applicant(s)** YAMAMOTO ET AL.	
	Examiner MAURY AUDET	**Art Unit** 1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 September 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See continuation sheet.*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Maury Audet/
Primary Examiner, Art Unit 1654

Continuation of Box 3. (a) and 7.

Although the amendments have been entered, they have raised new issues that would require further consideration and/or search.

Per Box 7, the amended claims would be rejected is provided herewith:

Claim Rejections - 35 USC § 102/103
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 99/36099 A1 (Takeda Chemical Industry, LTD; Saikawa et al.; Applicant's assignees earlier work and 1 inventor of present application: Yamamoto).

Applicant's earlier work in WO '099 teach a method of making sustained release compositions (title) the same compound formula species - 5-oxo-Pro-His-Trp-Ser-Tyr-Y-Leu-Arg-Pro-Z as a sustained release microcapsule or implant preparation, with Y being one of several D-amino acids and Z is Gly-NH2 or NHEt. AND more specifically 5-oxo-Pro-His-Trp-Ser-Tyr-DLeu-Leu-Arg-Pro-NHEt, identified in the specification as "Leuprorelin" - presently made (see entire document, e.g. compounds page 7; all claims, especially claim 11). Thus, Saikawa teaches each peptide member of the Markush group of instant claim 1 (e.g., page 8, lines 6-15 and claim 11). Saikawa teaches the acetate form of Peptide B in Example 11 (page 51).

Further, Saikawa teaches Leuprorelin as Peptide B, and the acetate form. Saikawa identifies Peptide B as an LHRH agonist. Saikawa teaches microcapsule formulation of Peptide B with lactic acid polymer (polylactic acid), e.g.- Examples 7 and 8 (pages 47-49). The retention rate of Example 8 Peptide B microcapsules are described in Table 2 (page 54) and further described as "sustained release preparations" with retention rate of 24 % of Peptide B after 20 weeks. Saikawa states that "the same bioactive substance release rate is maintained, demonstrating efficacy as a sustained-release preparation." (page 55).

The claimed peptides are anticipated, but in the event all aspects of the claimed sustained release formulation are not expressly claimed, it would have been obvious to one of ordinary skill in the art to have routinely optimized any of the formulation elements, e.g. molar amounts of the same polymer, used in WO '099 to have arrived at the presently claimed invention. Absent evidence of the contrary that the same is not present in WO '099 AND that any difference provided some unexpected result.
[By example, that such sustained release formulations (e.g. microcapsules/micospheres were being routine optimized on such parameters; as far back as 1989, Applicant submits in IDS 1/21/10, among other references cited in the corresponding JP appliation, 3 abstracts:
JP 1216918 (A), a 1989 reference explaining the same conversion of a sustained release composition comprising a poly-lactic acid, using acetic acid and forming the same into a W/O emulsion;
JP 2124814 (A) (also an earlier Takeda Chem. Ind.'s work) citing the 1 to 5 ratio of a hydrocarbon to the active agent; and
JP 4208217 (A) on the use of D,L-lactic acid and glycolic acid in like-kind compositions.].

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

THE EXAMINER DOES NOT FIND THAT APPLICANT HAS INFORMED THE OFFICE OF HIS EARLIER WORK IN WO '099, IN EITHER OF THE IDS's OF RECORD? APPLICANT IS ASKED TO PROVIDE THE ENGLISH LANGUAGE VERSION OF WO '099.